Express Mail Label No Ex 416449053 US FSUM 10442.19 PATENT

Art Unit: To Be Assigned

DEC 2 9 2003 &

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

application of: Robert Holton

Serial No.: 10/680,649 Filed: October 7, 2003

Confirmation No.: To Be Assigned For: TAXANE FORUMULATIONS

December 29, 2003

COMMISSIONER FOR PATENTS P.O. BOX 1450 ALEXANDRIA, VIRGINIA 22313-1450

SIR:

## **INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicant submits the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the Pre-OG notice of July 11, 2003 partially waiving the requirements of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S. patent documents are not supplied. Copies of references 35-49 and 51-59 have not been provided in accordance with 37 C.F.R. § 1.98(d) because they are of record in prior application Serial No. 09/776,426 (now U. S. Patent No. 6,638,973 B2) relied upon for an earlier filing date under 35 U.S.C. § 120. Copies of references 33, 34 and 50 are provided.

Respectfully submitted,

Edward J. Heilek, Reg. No. 31,525

SENNIGER, POWERS, LEAVITT & ROEDEL

One Metropolitan Square, 16th Floor

St. Louis, Missouri 63102

(314) 231-5400

EJH/dfw/dep \*Attachment

PTO/SB/0	8A DEC 2	9 2003	S)	Compl	ete if Known
II.	IFORMATION	I DISE	OSURE	Application Number	10/680,649
INFORMATION DISCLOSURE STATEMENT APPLICANT				Filing Date	October 7, 2003
(use as many sheets as necessary)			necessary)	Confirmation Number	To Be Assigned
				First Named Inventor	Robert A. Holton
Evores	A lade I licM a	lo EV/	116449053 HS	Group Art Unit	To Be Assigned
Express Mail Label No. EV 416449053 US		Examiner Name	To Be Assigned		
Sheet	1	of	5	Attorney Docket No.	FSUM 10442.19

			U.S. PATENT	DOCUMENTS		
		U.S. Patent D	ocument	No. 2 of Detector on Applicant of	Date of Publication of Cited	
Examiner Initials*	Cite No.1	Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Document MM-DD-YYYY	
3	1.	4,960,790		Stella et al.	10-02-1990	
	2.	5,175,315		Holton	12-29-1992	
	3.	5,227,400		Holton et al.	07-13-1993	
	4.	5,243,045		Holton et al.	09-07-1993	
	5.	5,250,683		Holton et al.	10-05-1993	
	6.	5,283,253		Holton et al.	02-01-1994	
	7.	5,350,866		Holton et al.	09-27-1994	
	8.	5,407,683		Shively	04-18-1995	
	9.	5,430,160		Holton	07-04-1995	
	10.	5,438,072	Α	Bobee et al.	8-01-1995	
	11.	5,439,686		Desai et al.	08-08-1995	
	12.	5,478,860		Wheeler et al.	12-26-1995	
	13.	5,527,537		Dietl	06-18-1996	
	14.	5,616,330		Kaufman et al.	04-01-1997	
	15.	5,681,846		Trissel	10-28-1997	
	16.	5,714,513	,	Holton et al.	02-03-1998	

		· · · · · · · · · · · · · · · · · · ·
Examiner	Date	
Signature	 Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

			<u>8</u>			
PTO/SB/0	08A	2 9, 2	003 32	Complete if Known		
ı	NFORMATION	DISC.	URE	Application Number	10/680,649	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	October 7, 2003	
(us	e as many shee	ts as	necessary)	Confirmation Number	To Be Assigned	
				First Named Inventor	Robert A. Holton	
Expres	ss Mail Lahel No	FV.	416449053 US	Group Art Unit	To Be Assigned	
Express Mail Label No. EV 416449053 US			110110000 00	Examiner Name	To Be Assigned	
Sheet	2	of	5	Attorney Docket No.	FSUM 10442.19	

	17.	5,721,268		Holton et al.	02-24-1998
	18.	5,877,205		Andersson	03-02-1999
	19.	5,922,754	"	Burchett et al.	07-13-1999
	20.	5,925,669		Katz et al.	07-20-1999
	21.	5,929,030		Hamied et al.	07-27-1999
	22.	5,965,603		Johnson et al.	10-12-1999
•	23.	5,972,992		Carver et al.	10-26-1999
	24.	5,977,164		Carver et al.	11-02-1999
	25.	6,140,359		Carver et al.	10-31-2000
	26.	6,359,154	B2	Holton	03-19-2002
	27.	6,596,737	B2	Holton et al.	07-22-2003
	28.	6,610,860	B2	Holton	08-26-2003
	29.	6,638,973	B2	Holton	10-28-2003
	30.	6,649,632	B2	Holton	11-18-2003
	31.	6,660,866	B2	Holton	12-09-2003
	32.	6,664,275	B2	Holton	12/16/03
	33.	2001/0029264	A1	McChesney-Harris	10-11-2001
	34.	2002/0058616	A1	Broder et al.	05-16-2002

	,	T	
Examiner	Date		
Signature	 Considered	· · · · · · · · · · · · · · · · · · ·	· .

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/	08A (2	\$ 700	C 22 3	Compl	ete if Known
ı	NFORMA TON	DIONS	LOSURE	Application Number	10/680,649
:	STATEMENT B	YAPI	PLICANT	Filing Date	October 7, 2003
(use as many sheets as necessary)				Confirmation Number	To Be Assigned
				First Named Inventor	Robert A. Holton
Evero	se Mail Labol Ne	<b>. ⊑</b> \/	416440053 US	Group Art Unit	To Be Assigned
Express Mail Label No. EV 416449053 US				Examiner Name	To Be Assigned
Sheet	3	of	5	Attorney Docket No.	FSUM 10442.19

1014

			FOF	REIGN PATE	ENT DOCUMENTS		
		F	oreign Patent D	ocument	Name of Datastas an Analisant of	Date of Publication of	
Examiner Initials*	Cite No. <sup>1</sup>	Office	Number⁴	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	T <sup>6</sup>
	35.	wo	94/13655	A1	The Upjohn Company	06-23-1994	
	36.	wo	95/11020	A1	Enzon, Inc.	04-27-1995	
	37.	wo	96/13495	A1	The Research Foundation of State University of New York	05-09-1996	
	38.	wo	96/38138	A1	Biophysica Foundation	12-05-1996	
	39.	wo	97/09979	A1	Florida State University	03-20-1997	
	40.	wo	97/32578	A1	The Research Foundation of State University of New York	09-12-1997	
	41.	wo	97/42181	A1	Florida State University	11-13-1997	
	42.	wo	98/02426	A1	Kabushiki Kaisha Yakult Honsha	01-22-1998	
	43.	wo	99/09021	A1	Florida State University	02-25-1999	
	44.	wo	99/14209	A1	Kabushiki Kaisha Yakult Honsha	03-25-1999	
· · · · · · · · · · · · · · · · · · ·	45.	wo	99/32473	A1	Kabushiki Kaisha Yakult Honsha	07-01-1999	
	46.	wo	00/53592	A1	Asahi Kasei Kogyo Kabushiki Kaisha	09-14-2000	
·	47.	wo	00/78247	A1	Baker Norton Pharmaceuticals	12-28-2000	
	48.	EP	0 534 709	A1	Florida State University	03-31-1993	

	 <del></del>	1	
Examiner	Date		
Signature	 Considered		

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

,	0'	~ · · · · ·	, yes		
PTO/SB/0	D8A	∑ 3.7m		Comple	ete if Known
1	NFORMATION	DISC	SOSURE	Application Number	10/680,649
;	STATEMENT B	YAPI	PLICANT	Filing Date	October 7, 2003
(us	e as many shee	ets as	necessary)	Confirmation Number	To Be Assigned
				First Named Inventor	Robert A. Holton
Evnres	ss Mail Label No	, EV.	416449053 US	Group Art Unit	To Be Assigned
Ехрісс	55 Mail Label 140	. <b> v</b>	110440000 00	Examiner Name	To Be Assigned
Sheet	4	of	5	Attorney Docket No.	FSUM 10442.19

	(	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	49.	GUENARD et al. "Effects of the Hydrophobicity of Taxoids on their Interaction with Tubulin" Bioorganic & Medicinal Chemistry, Vol. 8 (2000) pp. 145-156.	
	50.	International Search Report for analogous PCT Application No. PCT/US01/03624 dated June 12, 2001.	
	51.	KANT et al. "A Chemoselective Approach to Functionalize the C-10 Position of 10-Deacetylbaccatin .III. Synthesis and Biological Properties of Novel C-10 Taxol Analogues" Tetrahedron Letters, Vol. 35, No. 31 (1994) pp. 5543-5546.	
	52.	KIRIKAE et al. "Structural Significance of the Acyl Group at the C-10 Position and the A Ring of the Taxane Core of Paclitaxel for Inducing Nitric Oxide and Tumor Necrosis Factor Production by Murine Macrophages" FEBS Letters, Vol. 478 (2000) pp. 221-226.	
	53.	LIN et al. "Synthesis of Highly Potent Second-Generation Taxoids Through Effective Kinetic Resolution Coupling of Racemic β-Lactams with Baccatins" CHIRALITY, Vol. 12 (2000) pp. 431-441.	
	54.	OJIMA et al. "Efficient Asymmetric Synthesis of β-lactams Bearing a Cyclopropane or an Epoxide Moiety and Their Application to the Synthesis of Novel Isoserines and Taxoids" Journal of Organic Chemistry, Vol. 63, No. 2 (1998) pp. 224-225.	
	55.	OJIMA et al. "Synthesis and Biological Activity of Novel 3'-Trifluoromethyl Taxoids" Bioorganic & Medicinal Chemistry Letters, Vol. 7, No. 2 (1997) pp. 133-138.	
	56.	OJIMA et al. "Synthesis and Structure-Activity Relationships of New Second-Generation Taxoids" Bioorganic & Medicinal Chemistry Letters, Vol. 9 (1999) pp. 3423-3428.	
	57.	OJIMA et al. "Synthesis and Structure-Activity Relationships of the Second-Generation Antitumor Taxoids: Exceptional Activity Against Drug-Resistant Cancer Cells" Journal of Medicinal Chemistry, Vol. 39 (1996) pp. 3889-3896.	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

	· /	0000	16.			
PTO/SB/	DBA DEL Z	3 700	JOE :	Complete if Known		
ı	NFORMATION	ଧାୟଣ୍ଡ	S OSURE	Application Number	10/680,649	
:	STATEMENT B	API	PLICANT	Filing Date	October 7, 2003	
(use as many sheets as necessary)				Confirmation Number	To Be Assigned	
				First Named Inventor	Robert A. Holton	
Everes	ss Mail Label No	- E\/ .	41644Q053 US	Group Art Unit	To Be Assigned	
Expres	55 IVIAII LADEI IVO	v. ∟v ·	410443033 03	Examiner Name	To Be Assigned	
Sheet	5	of	5	Attorney Docket No.	FSUM 10442.19	

	58.	RAO et al. "Synthesis and Evaluation of Some 10-Mono- and 2',10-Diesters of 10-Deacetylpaclitaxel" Journal of Medicinal Chemistry, Vol. 38, No. 17 (1995) pp. 3411-3414.
	59.	SENGUPTA et al. "Probing the Environment of Tubulin-Bound Paclitaxel Using Fluorescent Paclitaxel Analogues" Biochemistry, Vol. 36, No. 17 (1997) pp. 5179-5184.
<u> </u>		
•		

		T	
Examiner	Date		
Signature	Considered		

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.